

Design and Validation of a Handheld Probe to Measure Knee Joint Sounds

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Abstract

The goal of this research is to design and validate a system used to record joint sounds measurements that can be collected at home by patients. Wearable and handheld technology allows patients to monitor conditions at home, eliminating the need for time-consuming and costly medical appointments.

In the United States, around 33% of adults have arthritis or other chronic joint pain conditions (CDC 2001). Due to the load placed on the knee and the reliance of the knee joint on soft tissues, knee joint conditions are the most common articular condition. The most common approach for diagnosing and monitoring knee joint disorders is physical examination, which yields poor diagnostic validity with the exception of the Lachman test for anterior cruciate ligament (ACL) injuries (Tanaka 2017). The clinical gold standard for diagnosing joint disorders is thus medical imaging, such as X-Ray or CT scanning, which poses financial challenges for patients and hospitals alike.

Patients are interested in at-home joint monitoring devices. In a focus group study of osteoarthritis patients, patients described the need for objective measures of treatment success that could be taken at home (Papi 2015). Existing joint monitoring devices focus on patient-reported outcomes and physical task performances, leaving quantitative measurements of joint conditions to clinicians. This work aims to validate a knee joint health tracking device for home use that can reduce the costliness and frequency of medical appointments.

1. Introduction

At-home health monitoring systems allow patients and their healthcare providers to track conditions outside of hospitals and clinics. Due to an aging global population and high prevalence of chronic disease, biomedical engineers are developing new biosensor technologies in “p-health” i.e. personal, preventive, patient-centered medicine (Zheng 2014). Advances in microelectronics, machine learning, and signal processing have made it feasible to design non-invasive biosensors that are small enough to wear or hold. In the last decade, health monitoring research has shifted to focus on replacing qualitative clinical assessments with quantitative measurements of physiological data. Often, biosensors collect data that is imperceptible to physicians. For these biosensors, validating that a particular physiological signal can be used as a diagnostic metric is equally as important as validating that the signal is being collected and filtered accurately.

In the 1990s, the earliest personal health monitoring systems focused on vital signs, such as heart rate, blood pressure, and temperature. To evaluate joint health, physicians often listen for crepitus, which is when the joint makes an audible crack or pop. Joints also make faint creaking sounds which are difficult to hear but can provide useful information on articular conditions. Research has been done to evaluate systems that use joint sounds as a diagnostic tool (Mascaro 2009, Teague 2016, Song 2018). These studies typically investigate the use of joint sounds for one-time diagnostics- providing a snapshot of joint health to replace similar snapshots provided by medical imaging such as MRIs or x-rays. However, the variation of joint sounds over time is more useful to understand the progression of a chronic articular condition such as arthritis (Inan 2018).

Small, portable or wearable health monitoring systems allow patients to capture information about their conditions outside of a clinical setting. Glucose monitors are one example of health technology successfully used to track a chronic condition over time, enabling diabetic patients to manage their blood sugar levels and provide more information to their health care providers. The proposed system would be used by patients at home, like a glucose monitor, but would track joint sounds rather than blood glucose levels. Biosensing systems for joint sounds have been proven effective at recognizing certain

conditions such as juvenile idiopathic arthritis (Semiz 2017) and ACL injuries (Tanaka 2017). However, little research has been done to assess the validity of repeated joint sounds measurements to track chronic conditions.

The purpose of this work is to design and validate an at-home joint sounds monitoring device that can be used to assess the progression of a knee joint condition over time. The design of the device includes establishing design requirements, determining acceptance criteria, and modeling and manufacturing a prototype of the device. Validation of the device will test the device performance in human models to ensure that knee joint sounds can be collected with the novel monitoring system.

2. Literature Review

Arthritis is the most common cause of disability in American adults (Hootman 2012). In the United States, arthritis affects around 53 million adults and joint pain affects 70 million adults. The estimated annual costs including healthcare and loss of productivity for these two groups are \$65 billion and \$60 billion, respectively. (Gaskin 2012). Osteoarthritis (OA) and rheumatoid arthritis (RA) are the most common types of arthritis. OA is caused by the gradual deterioration of cartilage as patients age while RA is an inflammatory autoimmune condition (Hootman 2012).

A study of at-home medical device use in elderly patients found that patients using monitoring devices often reported a greater sense of control over their conditions (Thomson 2013). Earlier and more frequent measurements of the progression of a joint condition, especially conditions like RA that can lead to permanent damage if not treated early, might allow healthcare providers to assess and adjust pharmacological treatments in a more timely manner (Pietsky 2017). There is little data on devices that can monitor joint conditions, but a meta-analysis of remote monitoring for patients with cardiac conditions showed a significant decrease in deaths for those patients who used remote monitoring medical devices (Klersy 2009).

Existing technologies for at-home monitoring of joint conditions include apps, wearable devices, and handheld tools. A review of 19 apps found a lack of quality in the RA monitoring apps available using the Mobile App Rating Scale, a scale used to measure the effectiveness of mobile health apps. Only 1 app of 19 included both a validated tracking measure and the ability to share data with healthcare providers. (Grainger 2017) The validated tracking measure used by this app was the 28-joint disease activity score, or DAS28, which is self-reported by the patient.

Patients are interested in wearable technology that can be used at home. According to a recent survey by the Johns Hopkins Department of Orthopedic Surgery of patients that have been diagnosed with degenerative joint disease, over 50% of participants were interested in using a wearable activity monitoring device to track their condition (Kane 2017). Using a probe to monitor knee joint sounds could be more effective for children than wearable technology. Developing wearable health monitoring systems

for pediatric applications comes with unique design challenges related to regulatory compliance and patient growth. Another unique benefit of a handheld probe design is the potential to be expanded to monitor more than one joint, which would be especially beneficial for RA patients. Finally, a hand-held probe could be used by more than one patient and does not require anatomy-specific design. For example, a physical therapist may send patients home with a hand-held tool for the duration of an injury treatment, which could later be sanitized and re-used. Handheld probes address a different target population than wearable devices in monitoring joint conditions, yet development efforts have focused mainly on wearable systems.

Only one handheld tool exists for monitoring joint conditions- the e-Ouch. The e-Ouch is a handheld pain diary used to assess pain for JIA patients. From a sample of 10, all adolescents who used the e-Ouch pain diary said it was easy to learn and use. (Stinson 2006). However, the e-Ouch provides a qualitative assessment of the condition, rather than a quantitative assessment.

In summary, there are few at-home monitoring devices for joint conditions. Existing devices focus on subjective, qualitative assessments of pain and movement. Quantitative measurements of joint conditions are taken in clinical settings via radiographic imaging. The proposed work would fill the need for a quantitative at-home health monitoring system for patients with knee joint conditions.

3. Methods

3.1 Design requirements

The system includes 3 main components: a microcontroller for data collection, a MEMs microphone, and a handheld probe to house the microphone. The components were selected based on previous joint sounds collection protocols (Bolos, 2019, Whittingslow, 2020) that used MEMs microphones to collect healthy and disordered knee joint sounds and based on the identified need for a handheld system. To select one design from the top 4 probe design choices, a decision matrix was created with each of the design requirements.

The criteria in the decision matrix were chosen based on user need, safety, and performance. Criteria 1 and 2 pertain to the user need for a handheld device that can collect joint sounds using MEMs microphones. Criteria 3, 4, and 7 pertain to the control of force in the design to prevent joint sounds signal interruption from contact forces (Bolos, 2019). Criteria 5 and 6 pertain to the user interface, ensuring that the system can be used in a home setting with a typical power source and accessible data interface.

Table 1- Design Requirements Decision Matrix

Design ideas/ Design requirements	Design 1- Spring loaded probe	Design 2- Slider probe	Design 3- Piezoelectric force sensor probe	Design 4- Cushioned tip probe
1. Can collect joint sounds using MEMs microphones	1	1	1	1
2. Handheld	1	1	1	1
3. Has a mechanism to prevent the microphone from pressing too firmly into the skin	1	1	1	1
4. Has a mechanism to ensure that microphone contact with the skin is not interrupted	1	0	0	1
5. Powered either by standard batteries, rechargeable batteries or wall outlet power	1	1	1	1
6. Has a way to easily access recordings e.g. via data cable	1	1	1	1
7. Ensures that a consistent force is applied to the skin	1	0	0	0
Total	7	5	5	6

The spring loaded probe scored highest in the decision matrix, so this was the final design concept selected for this research.

The body of the probe is made of 3D printed PLA. The system includes the probe body, a MEMs microphone, a microcontroller, and a battery. The range of forces acceptable for the system to apply to the knee joint while collecting joint sounds is 4-7 N (Bolus 2019).

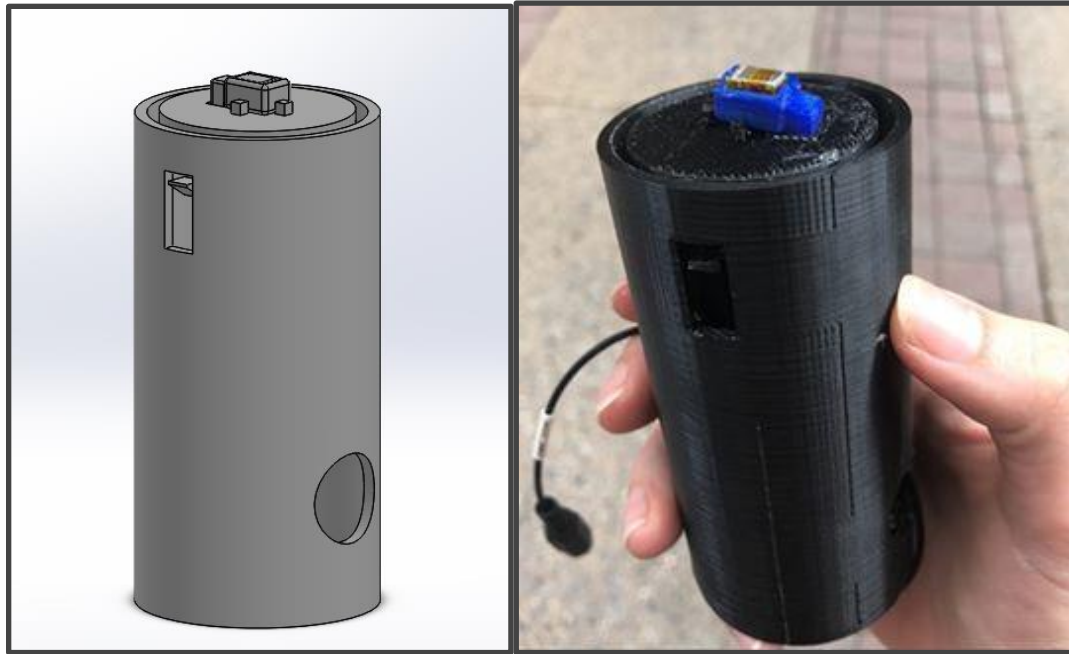


Fig. 1- 3D Rendering and Photo of Joint Sounds Probe System

3.2 Establishing consistency of applied force

When the applied force of a MEMs microphone to a joint is outside of a range of 5-10 N, the accuracy of joint sounds recordings declines greatly (Bolus, 2019). The following protocol is to determine the applied force of the joint sounds probe MEMs microphone on the knee. High contact forces push the microphone into the skin, causing the skin to pucker and changing the characteristics of joint sounds being recorded.

In the following protocol, healthy subjects will perform seated knee flexion-extension cycles with a force sensor adhered to the skin above the patellar tendon. The subjects will hold the joint sounds probe against this sensor during the flexion-extension cycles as if recording joint sounds at home. No recordings will be created during this experiment as the force sensor interferes with joint sound recordings. An inertial measurement unit (IMU) placed near the ankle of the subject will measure the knee joint angle over time so that applied force vs. knee joint angle can be determined.

3.2.1 Applied Force Experimental Protocol

Materials:

Adhesive pads

Joint sounds probe

Inertial measurement unit (IMU)

Arduino (x2)

SingleTact force sensor Arduino firmware and software

Force sensor

1. Plug the force sensor into the Arduino and connect the force sensor Arduino to the laptop. Open force testing software module.
2. Plug the IMU into the 2nd Arduino and connect the IMU Arduino to the laptop.
3. Make sure the subject is seated comfortably in a chair in an area where they can easily flex and extend the legs.
4. Using a double sided adhesive pad, attach a force sensor at the knee joint to the lateral side of the patellar tendon on the right knee.
5. Attach an inertial measurement unit (IMU) to the right leg 5 mm above the lateral side of the ankle to measure the angle of the knee joint.
6. Before the first trial on each leg, ask the subject to do a practice trial of at least one flexion extension cycle. Don't allow the leg or foot to hit the ground during flexion-extension cycles.
7. Align the microphone of the joint sounds probe over the force sensor. Have the subject press the probe into the knee to the point where the rim of the probe is lightly touching the skin and the spring is engaged such that the microphone is firmly in contact with the skin. Note: in this experiment, no audio recordings will be made.
8. With the assistance of Daniel Whittingslow's flexion extension animation, subject will perform 3 trials of 10 flexion extension cycles lasting 4 seconds per cycle while recording the forces and joint angles. Again, ensure that the leg or foot does not hit the ground.
9. Extract the data from the IMU and the force sensor using Arduino data collection modules. Plot the graphs of the joint angles and forces in MATLAB to check for signal quality.
Repeat for the right knee, medial side, and left knee patellar and medial sides.

3.3 Establishing repeatability of joint sounds signal collection

5-10 healthy subjects will perform seated flexion-extension tests with the joint sounds probe system, including the microphone, held to the knee joint in 4 locations- laterally and medially to the patellar tendons on right and left legs. . The tests will be performed with 10 cycles per knee with cycles lasting for 4 seconds. The purpose of this protocol is to establish how consistently joint sounds can be collected with the novel handheld monitoring system. For healthy subjects, each flexion-extension cycle will produce sounds similar to the other flexion-extension cycles for that recording location.

3.3.1 Joint Sounds Collection Experimental Protocol

Materials:

Adhesive pads
Joint sounds probe
Microphone (Attached to probe)
Joint sounds data acquisition device
Inertial measurement unit (IMU)
Arduino (x2)
HeartPulse App software
Velcro strap

1. Plug the IMU into the Arduino and connect the IMU Arduino to the laptop.
2. Gather the joint sounds data acquisition device.
3. Make sure the subject is seated comfortably in a chair in an area where they can easily flex and extend the legs.
4. Use a Velcro strap to strap the joint sounds data acquisition device to the subject's right thigh a few inches above the knee.
5. Plug the microphone of the joint sounds probe into the data acquisition device.
6. Attach an inertial measurement unit (IMU) to the right leg 5 mm above the lateral side of the ankle to measure the angle of the knee joint.
7. Before the first trial on each leg, ask the subject to do a practice trial of at least one flexion extension cycle. Don't allow the leg or foot to hit the ground during flexion-extension cycles.
8. Align the microphone of the joint sounds probe over the skin lateral to the patellar tendon on the right knee. Have the subject press the probe into the knee to the point where the rim of the probe is lightly touching the skin and the spring is engaged such that the microphone is firmly in contact with the skin.
9. With the assistance of Daniel Whittingslow's flexion extension animation, the subject will perform 3 trials of 10 flexion extension cycles lasting 4 seconds per cycle while recording the joint sounds and joint angles. . Again, ensure that the leg or foot does not hit the ground.
10. Extract the data using HeartPulse App and the IMU Arduino data collection module.
11. Plot the graphs of the joint sounds and forces in MATLAB to check for signal quality.
Repeat for the right knee, medial side, and left knee patellar and medial sides.

3.4 Statistical Analysis

Statistical analysis will include use of the intra-class correlation coefficient (ICC) to show consistency between signals collected with the device. Each subject will be one group and the intra-class correlation coefficient will describe the similarity between the flexion-extension cycles for that subject. For the force sensor data, the variance will be calculated to show the fluctuation in applied contact force.

4 Results

The force sensor delaminated during trials with subject 1, and an equivalent replacement force sensor was not found for subjects 2 and 3. Due to the disruption of COVID-19, I was unable to return to campus to continue the force sensor testing. The mean contact forces and variance in contact forces are shown in Table 2, but it should be noted that the delamination likely occurred during the first trial, meaning that all force sensor results do not accurately represent the contact force of the microphone with the knee joint. With a variance of between 3.5 and 5 Newtons, the data shows either that contact force varied greatly as cycles continued, or more likely, that the signal was regularly interrupted for long periods of time, which corresponds with findings from plotted data.

	Left Lateral	Left Medial	Right Medial
Mean Force (N)	0.0123	0.0128	0.0107
Variance	4.142	4.924	3.698

Because the force data was unreliable, the intra-class correlation coefficient (ICC) results are necessary to determine whether this system provided a means for consistent joint sounds recording.

Figure 2 shows a sample of joint sounds and IMU data collected during this experiment.

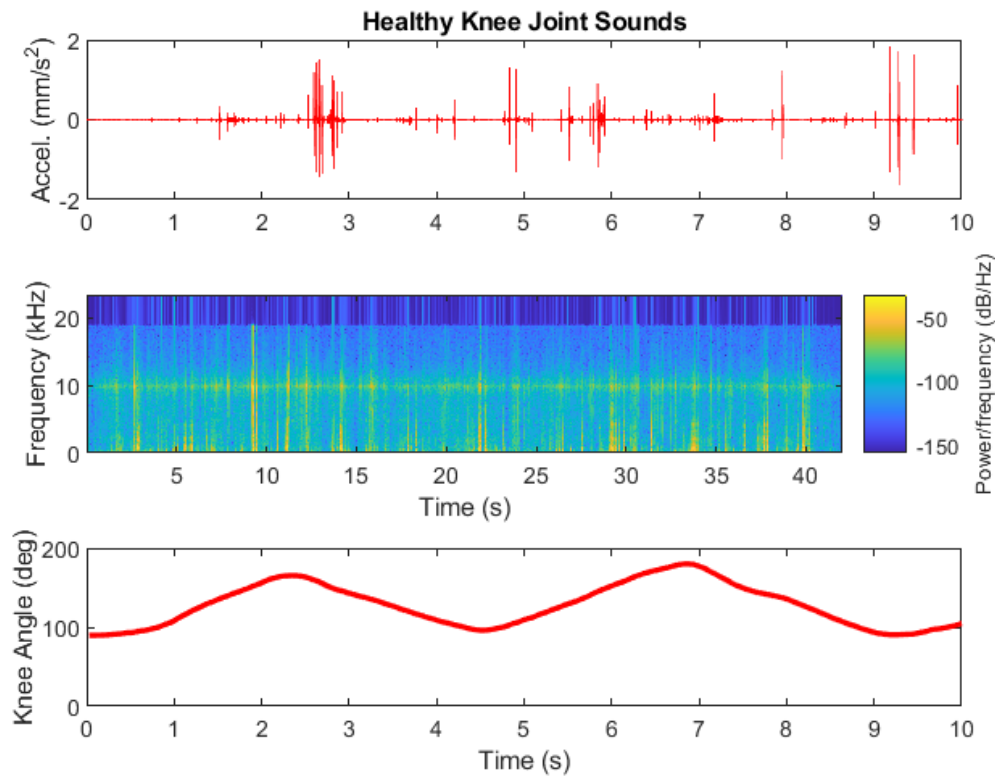


Fig. 2 Knee Joint Sounds, Frequency Spectrum, and Knee Joint Angle vs. Time

Intra-class correlation coefficient, or ICC, is a measure of how strongly the measurements in one group resemble one another. In this case, each trial is one group. Each subject has completed 12 trials- 3 trials per side of knee per leg. The trials were split into 10 flexion extension cycles using data from the IMU to determine the knee joint angle. A high ICC value indicates high conformity in the data in one group. Healthy knee joints produce similar sounds in each flexion extension cycle, so the data should show a high similarity in knee joint sounds for all 10 cycles in one trial if the probe is collecting knee joint sounds consistently. While the target number of subjects for this experiment was $n=5$, only 3 subjects enrolled in the study before campus and laboratory closure due to COVID-19. The ICC values are for 3 subjects with 12 trials per subject, a total of 36 trials. The ICC for these 36 trials resulted in a mean ICC of 0.9708, with a confidence interval [0.9407, 0.9900]. This high ICC value shows that the recordings created with the novel knee joint sounds probe were consistent across cycles for each trial.

5 Discussion

Future work in this area can develop this form factor for at-home use in joint health monitoring. The design of the probe is not highly specific to either the physiology of a certain patient, or the physiology of a particular joint. The form factor could be used as an all-in-one at home monitoring system for multiple joints in patients with arthritis, injuries and other joint health conditions. Clinicians can use a single joint sounds recording to determine a snapshot of knee health, but the value of additional monitoring lies in the ability to measure treatment efficacy and patient joint health over time. Since joint sounds vary greatly from person to person, establishing a baseline of normal joint sounds can increase the ability to detect when a patient deviates from a healthy state.

While some of the ongoing research in the joint monitoring space is focused on wearable form factors, this form factor has unique strengths. A hand-held monitoring system is appropriate for individuals who may not be able to get full use of a wearable system. This form factor shows promise for joint health monitoring in very young children, people with many disordered joints, people with sensory processing issues, or children and adults who are very active in sports or physically demanding jobs that may interfere with wearable use. The choice in spring in this system can be investigated to determine the ideal spring constant parameters for delivering appropriate contact forces between the microphone and the skin. Further research is needed to confirm the joint sounds ICC results with a higher number of subjects and to perform force sensor testing with a working force sensor. The preliminary ICC results from 3 subjects show that this system is promising for gathering knee joint sounds data, but further evidence is required before the system can be implemented in a clinical or home setting.

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